#### REMARKS

#### Status of the Claims

Applicant appreciates the Examiner's acknowledgement that claims 1-13, 25 and 37-60 are currently pending examination for patentability. In turn, Applicant acknowledges the accidental strike-through of the claim number for both of amended claims 13 and 25. Applicant has herein canceled both claims rendering this objection moot. Applicant also presents amended claims 1-3, 6, 8-10, 12, 37-38, 40, 43, 45-46, 49-50, 52-57 and 59-60 and all amendments were made without prejudice or disclaimer of the subject matter thereof.

### Rejection Of Claims 53-60 under 35 U.S.C. 112, Second Paragraph

The Examiner has rejected claims 53-60 under 35 U.S.C. 112, second paragraph for the reasons of record.

Specifically, the Examiner has stated that claims 52, 53, 55, 56, 58 and 59 include the limitation, "[t]he method of claim 50," which does not have sufficient antecedent basis for this limitation in the claim. Applicant has amended all such claims to address this objection.

Although the Examiner did not specifically include claims 54 or 57, both claims have been amended in the same manner as claims 53, 55, 56, 58 and 59.

The Examiner has also stated claim 59 that includes the limitation, "wherein the bacteria is" does not have sufficient antecedent basis. Applicant has amended this claim to address this objection.

In view of the foregoing amendments, Applicant respectfully requests withdrawal of the Examiner's rejection of claims 53-60 under 35 U.S.C. 112, second paragraph.

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# Rejection of Claims 50, 52, 53, 59 and 60 under 35 U.S.C. 101

The Examiner has rejected claims 50, 52, 53, 59 and 60 under 35 U.S.C. 101 as directed to nonstatutory subject matter for the reasons of record. Specifically, the Examiner has rejected the claims as being directed to a naturally occurring product which is not patentable.

The Examiner appears to have misunderstood Applicant's invention which is directed to an antibacterial component isolated from hyperimmune colostrum or hyperimmune milk and not milk itself. In response to this misunderstanding and, in order to expedite allowance of claims, Applicant has amended independent claim 50 to clearly distinguish the claimed invention from a naturally occurring product, such as milk.

In view of the foregoing amendments and comments, Applicant respectfully requests withdrawal of the Examiner's rejection of claims 50, 52, 53, 59 and 60 under 35 U.S.C. 101.

Rejection of Claims 1-4, 6, 8, 12, 13, 25, 37, 38, 40, 41, 43, 45 and 49 under 35 U.S.C. 102(b)

The Examiner has rejected claims 1-4, 6, 8, 12, 13, 25, 37, 38, 40, 41, 43, 45 and 49 under 35 U.S.C. 102(b) as being anticipated by Casswall et al. (Bovine Anti-Helicobacter pylori Antibodies for Oral Immunotherapy, Published 2002) as evidenced by Hemling (Iodine in Milk, Published 10/18/2001) and Dial et al. (Antibiotics Properties of Bovine Lactoferrin on Helicobacter pylori, Published 1998).

As an initial matter, claim 25 has been canceled rendering the rejection for this claim moot.

In order for an Examiner to establish a proper rejection under 102(b), the Examiner must show that each and every one of the claim limitations was suggested or taught by the prior art being relied upon. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Additionally, "[a]ll

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words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Applicant respectfully submits that the Examiner has not overcome this burden. As set forth in the record, Caswell et al. describes a method of using an immunoglobulin containing colostral product from cows hyperimmunized with *H. pylori* to inhibit *H. pylori* adherence to gastric mucosa and to Lewis blood group antigens. As also set forth in the record, Hemling discloses that milk may contain low levels of iodine and Dial et al. discloses that lactoferrin is present in colostrum and may have antibiotic properties against *H. pylori*.

In view of the current amendments to both independent claims 1 and 37, in which the claims are directed to administration of a composition including both a mucolytic agent and an antibacterial component, none of the cited references teach each and every element of the claimed invention, as required to make a proper rejection under U.S.C. 102(b). The amendments should render both claims novel and nonobvious.

In view of the foregoing, Applicant respectfully requests withdrawal of the Examiner's rejection of claims 4, 6, 8, 12, 13, 25, 37, 38, 40, 41, 43, 45 and 49 under 35 U.S.C. 102(b).

Rejection of Claims 5, 7, 9, 10, 11, 39, 42, 46, 47, 48, 51, 54, 55, 56, 57 and 58 under 35 U.S.C. 103(a)

The Examiner has rejected dependent claims 5, 7, 9, 10, 11, 39, 42, 46, 47, 48, 51, 54, 55, 56, 57 and 58 under 35 U.S.C. 103(a) as being unpatentable over Casswall et al. (Bovine Anti-elicobacter pylori Antibodies for Oral Immunotherapy, Published 2002) in view of Burggraber et al. (U.S. Patent Application 2003/0180381 A1, Published 09/25/2003) and as evidenced by Dial et al. (Antibiotic Properties of Bovine Lactoferrin on Helicobacter pylori, Published 1998).

As mentioned above, independent claims 1 and 37 were amended in order to render them novel

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and nonobvious. Claim 50 was also amended to distinguish the claimed invention from a naturally occurring milk product. All claims rejected under 35 U.S.C. 103(a) dependent from those amended claims.

In order for an Examiner to establish a prima facie case of obviousness, the Examiner must show that each and every one of the claim limitations was suggested or taught by the prior art being relied upon. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Additionally, "[a]l words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). When an independent claim is deemed nonobvious under 35 U.S.C. 103, then all claims depending therefrom are nonobvious as well. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988).

Furthermore, to support an obviousness rejection, MPEP §2143.03 requires, "all words of a claim to be considered" and MPEP §2141.02 requires consideration of both the, "invention and the prior art reference as a whole." The Board of Patent Appeal and Interferences also recently confirmed that a proper, post-KSR obviousness determination still requires the Office to make a, "searching comparison of the claimed invention – including all its limitations – with the teachings of the prior art." In re Wada and Murphy, Appeal 2007-3733, citing In re Ochiai 71 F.3d 1565, 1572 (Fed. Cir. 1995) and CFMT v. Yieldup Intern. Corp. 349 F.3d 1333, 1342 (Fed. Cir. 2003). As such, it is a well-settled principal in the law that an obviousness rejection requires the Examiner to address all elements in a rejected claim.

Applicant respectfully submits that all of the rejected claims are dependent claims and that a prima facie case of obviousness has not been made by the Examiner for any of the independent claims from which all rejected claims depend. As such, the Examiner has not overcome the burden as required for him to make an obviousness rejection as the cited references do not alone or in combination teach each and every element of the claimed invention. Additionally, Applicant herein cancels claims 51 and 58 rendering this rejection to those claims moot.

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In view of the foregoing, Applicant respectfully requests withdrawal of the Examiner's rejection of claims 5, 7, 9, 10, 11, 39, 42, 46, 47, 48, 51, 54, 55, 56, 57 and 58 under 35 U.S.C. 103(a)

## **Concluding Comments**

In view of the foregoing, Applicant respectfully submits that all claims are in condition for allowance. In the event the Examiner has any questions regarding the Applicant's position, a telephone call to the undersigned representative is requested.

Respectfully Submitted,

1-0-09 Date

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